

REMARKS/ARGUMENTS

In connection with the Request for Continued Examination filed herewith and responsive to the Final Office Action mailed March 22, 2006, Applicants respectfully request the Office to enter the following amendments and consider the following remarks. By this response, Applicants amend claim 1, and neither cancel nor add any other claims. After entry of this paper, claims 1-18 and 23-24 will remain subject to examination in this application.

In the Office Action, the Examiner (i) rejected claims 1, 2, 6-18, 23 and 24 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,762,049 to Zou *et al.* ("Zou"), in view of U.S. Patent No. 6,203,683 to Austin *et al.* ("Austin"), in further view of U.S. Patent No. 6,719,449 to Laugharn *et al.* ("Laugharn"); and (ii) rejected claims 3-5 under 35 U.S.C. § 103(a) as being unpatentable over Zou, in view of Austin and Laugharn, in further view of U.S. Patent No. 5,599,502 to Miyazaki *et al.* ("Miyazaki").

Applicants thank the Examiner for the helpful and productive interview of June 1, 2006, during which potential clarifications of independent claim 1 to further define over the cited art were discussed. The arguments/reasons discussed are consistent with those set forth below. This summary is in accord with 37 C.F.R. § 1.133(b), thus no further written statement regarding the interview is believed necessary at this time.

35 U.S.C. § 103(a) Rejections

With regard to the rejections under 35 U.S.C. § 103, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. Nevertheless, Applicants have amended claim 1 in the interest of expediting prosecution and avoiding additional costs. Applicants submit that amended claim 1 further clarifies the invention such that the cited references even more clearly do not teach or suggest all of the limitations of the claims.

Zou, Austin, and Laugharn

Claims 1, 2, 6-18, 23 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zou, in view of Austin, in further view of Laugharn.

Without acquiescing to the rejection and in the interest of expediting prosecution, Applicant has amended claim 1 to further clarify the recited invention over the cited art.

Specifically, claim 1 has been amended to recite a “point-of-care miniature analytical device with thermal regulation comprising: a cartridge comprising one or more portions constructed of a material ... wherein the cartridge portions include clear or translucent portions that allow direct irradiation of reactant molecules to facilitate thermal regulation of the reactants.” No new matter has been added via these amendments. Applicant respectfully asserts that Zou, Austin, and Laugharn do not teach or suggest the combination of features recited in amended claim 1.

Regarding the substance of the claim rejections, Applicants submit that the structures recited in claim 1 better establish the non-obviousness of the present invention and even further clarify the claimed invention over the cited art. For example, the claimed invention is drawn to a “miniature analytical device,” defined in the specification as “a device for conducting chemical and biological analytics tests ('assays') on a smaller scale as related to bench-top analytical equipment” (paragraph 5). In contrast, Zou is a larger device designed for use with bench- or base-related PCR elements such as external temperature balancing blocks, PCB (printed circuit board) thermal heating units, and “large heat sink[s]” (Zuo, col. 2, lines 36-48). Austin is also directed to a larger, PCR-type device that “includes data analysis equipment for the control of [] operations, and imaging equipment for the analysis of products. The bench-top apparatus of Laugharn also includes processors, computer programs, feedback systems, and other elements associated with such larger scale equipment. Thus, Applicants submit that claim 1 is distinguishable for this reason alone. Nevertheless, claim 1 has been even further distinguished from the cited art by clarification that the claimed invention is drawn to “point-of-care” devices directed to smaller volumes than bench-top devices (see, e.g., paragraph 11). The incorporation of the recited structures and thermal regulation elements into the present point-of-care miniature analytical device provide the very advantages articulated in the specification, yielding an invention with features such as decreased power consumption and other associated advantages that are not obvious in view of the cited bench-top art. See, for example, paragraphs 5, 9, 11-12, and 14.

For at least the above reasons, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. §103(a) be withdrawn and the claim allowed. Additionally,

claims 2, 6-18, 23 and 24, which directly or indirectly depend from claim 1, are also allowable for at least the same reasons.

Zou, Austin, Laugharn, and Miyazaki

Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Zou, in view of Austin and Laugharn, in further view of Miyazaki.

Claims 3-5 directly or indirectly depend from amended claim 1, and are allowable over the combination of Miyazaki with Zuo, Austin, and Laugharn for at least the reasons set forth in Applicants previous Response. See, e.g., Amendment and Response filed Dec. 20, 2005, pages 12-13. Miyazaki discloses a method and device for "feeding a slight quantity of liquid without any pulsating flow." Miyazaki, col. 1, lines 62-63. Miyazaki is directed to measurement and flow, and does not include elements such as an "optical temperature monitor" as explained in Applicants previous Response or "portions that allow direct ... thermal regulation" of reactants in each zone, as articulated above. Further, these various deficiencies of the presently-amended claims are cured neither by the addition of Laugharn (see above), nor by the knowledge of one skilled in the art. Thus, the instant combination of references fails to teach or suggest the recitations of claims 3-5, as amended herein. Accordingly, Applicants respectfully request that the rejection of claims 3-5 under 35 U.S.C. § 103(a) be withdrawn and the claims allowed.

Neither the motivation/suggestion to combine, nor the expectation of success exist

Additionally, Applicants respectfully submit that the Office has failed to meet it's burden of showing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness under § 103, "[f]irst, there must be some suggestion or motivation . . . to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success." M.P.E.P. § 2143 (8th ed., rev. 4, Oct. 2005). With regard to both the motivation/suggestion to combine and the expectation off success, Applicants submit that the Office has failed to demonstrate sufficient evidence to establish the basis to combine the cited references. Accordingly, Applicants also request that the rejections be withdrawn on these grounds.

Regarding its case for obviousness, the Office merely makes conclusory statements such as that: “[i]t would have been obvious to one of ordinary skill in the art to provide a feedback loop as taught by Austin et al. and/or Laugharn et al. as a means to regulate the heater as would be desirable for maintaining controlled temperature in analyses such as DNA analysis” (sentence bridging pgs. 6-7), and “[i]t would have been obvious ... to provide an infrared laser as taught by Miyazaki et al. as the infrared light source in the invention taught by [Zou/Austin/Laugharn] because Miyazaki et al. teach that a laser producing infrared light provides the advantage of heating liquid during a reaction ... and an infrared laser is a type of infrared light source that is generally disclosed by Austin et al. and Laugharn et al.” (OA, pg. 7, lines 12-18). However, in rejecting an application based upon obviousness, the Office “must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them.” *In re Rouffet*, 149 F.3d 1350, 1359 (Fed. Cir. 1998). Even though every element or feature of a claimed invention might readily be found in various references, mere identifying the elements/features is not sufficient to negate patentability. *Id.*, at 1357. Instead, “the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.” *Id.* Here, the Office provides no reason why the skilled artisan would select and combine the claimed features from those described in each reference, thus the rejections are improper.

The Office also argues that “one of ordinary skill in the art would have a reasonable expectation of success in modifying the Zou et al. reference to provide an infrared heater and sensor, given the teachings of Laugharn that an infrared thermal measuring device provides a non-contact means of analysis” (OA, pg. 4, lines 18-21). However, the reasons behind motivation must be supported by objective facts, into which the Office is obligated to thoroughly inquire. *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). Here, again, the Office has not cited any evidence of specific reasons for motivation nor identified where such evidence might be found. Instead, the Examiner relies solely upon a broad conclusory statement of the sort that the Federal Circuit has explicitly disclaimed. *In re Dembiczak*, 175 F.3d

994, 999 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'").

Moreover, the Office fails to establish both the rationale for combining and the expectation of success for each of the cited references, and thus the case for obviousness is logically deficient. For example, the Office provides no rationale (motivation or suggestion) at all as to why one would have **combined** Laugharn with the other references. Similarly, the Office provides no basis as to why one would expect to succeed in combining Miyazaki with the other references to achieve the claimed invention. Absent such necessary logical bases -- e.g., why an ordinary artisan would modify PCR-type devices like Zou and Austin using features from unrelated sonic energy devices like Laugharn -- Applicants submit these rejections cannot be maintained.

In summary, the case presented by the Office lacks the necessary logical and factual bases required to establish a *prima facie* case of obviousness, particularly with regard to the presently-amended claims. For these additional reasons, Applicants respectfully submit that the rejections should be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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